

#### IV. AMENDMENTS TO THE DRAWINGS

--- Replacement and annotated mark-up drawing sheets for amended figures showing the amended figures, if any, are attached at the Appendix hereto. Each figure is in compliance with 37 C.F.R. § 1.84. An explanation of the changes, if any, is set forth below in this “Amendments to the Drawings” section. Replacement drawing sheets are identified in the top margin as “Replacement Sheet.” Any replacement drawing sheet including amended figures includes all of the figures appearing on the immediate prior version of the sheet. Any annotated drawing sheets, if the same are required by the Examiner, are identified in the top margin as “Annotated Marked-Up Drawings.” Any deleted figure is noted by an instruction to delete the figure. Any corresponding amendment to the specification necessary to be made because of an amendment to the drawings in this section is made in the corresponding “Amendments to Specification” section.

- THE DRAWINGS OF THE PATENT IS HEREBY AMENDED AS SET FORTH BELOW:
  - *No Drawings are Present in this Application*
  - *Attachments: None*

## V. REMARKS/ARGUMENTS

- STATUS OF THE CLAIMS

Claims 1, 5, 14 and 15 are pending in this application. There are no amendments to the claims.

- REJECTIONS

- REJECTION UNDER 35 U.S.C. §112, First Paragraph

- Examiner's position

The Examiner has withdrawn his rejection of claims 1, 5, 14 and 15 under 35 U.S.C. § 112, first paragraph.

- Applicants' Response

N/R

- REJECTION UNDER 35 U.S.C. §112, Second Paragraph

- Examiner's position

The Examiner has withdrawn his rejection of claims 1, 5, 14 and 15 under 35 U.S.C. § 112, second paragraph.

- Applicants' Response

N/R

REJECTION UNDER 35 U.S.C. §103(a)

- Examiner's Position

The Examiner has deemed moot previous responses regarding the rejections of Claims 1, 5, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over DE 1927394 to inventor Wernecke. The Examiner has asserted a new ground for rejection.

The Examiner now rejects Claims 1, 5, 14 and 15 under 35 U.S.C. 103(a) as being unpatentable over the reference “Western Communion Hosts” in view of United States Patent No. 3,836,680 to inventor Salza.

It is the Examiner’s opinion, stated on page 2 of the office action, that “Western Communion Hosts” discloses a recipe, a need for gluten-free altar bread, and that altar bread prepared from substances other than wheat are invalid in view of the Canons of the Roman Catholic Church. It is also Examiner’s opinion that “Salza offers a solution” to one skilled in the art by teaching the substitution of traditional pasta (or wheat flour mixture) ingredients with a mixture of ungelatinized and pre-gelatinized wheat starch. Because such a product, according to the Examiner, is made solely of water and wheat ingredients it would satisfy the strict communion bread requirements. The Examiner deems that differences in the proportion of water to starch taught in the Salza patent versus the instant claims are attainable for those skilled in the art.. Although the Salza reference is silent on the proportion of pre-gelatinized starch to non-gelatinized starch, The Examiner argues the proportions of the instant claims would be obvious to one skilled in the art, being motivated by the teachings of “Western Communion Hosts.”

Concerning the water temperature of the instant claims 1 and 5, it is also the Examiner’s assertion that the Salsa reference discloses warm water in the starch mixture – specifically a temperature of 60<sup>0</sup> C, prior to the addition of adding non-gelatinized starch. Finally the Examiner deems that the “baking steps” and shaping of the wafer would be obvious to one skilled in the ar, as motivated by the “Western Communion Hosts” reference.

- Applicants' Response

The Applicants respectfully traverse the rejections of claims 1, 5, 14 and 15 under 35 U.S.C. §103(a).

The Applicants assert that the prior art references cited by the Examiner do not provide sufficient grounds for establishment of a *prima facie* case of obviousness, as set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), the factors be summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art. \*
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

The Applicants further call the Examiner's attention to MPEP 2143.03, which states that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.

With respect to instant independent claim 1, the limitations require, in part:

“A low-gluten wafer pre-cooked mixture consisting of: about 50% of a mixture of wheat starch and pre-gelatinized wheat starch to form a first homogeneous mixture combined with 50% of water, said water being at a temperature of between about 100 degrees Fahrenheit and about 150 degrees Fahrenheit to form a second homogeneous mixture,...”

Claim 1 claims a method of preparing low gluten wafers derived solely of wheat without corruption from additives or other agents such as emulsifiers that are used as substitutes for gluten. In doing so, the method provides an unmet need for those suffering from alimentary track disorders relating to the consumption of wheat while satisfying the general requirements of

the Roman Catholic Church<sup>1</sup> for the composition of the wafer. The claim provides an unexpected method of providing a sufficient consistency in the first and second homogeneous mixtures required for processing.

This is patently distinct from Salza, who discloses:

The fundamental problem, connected with the manufacture of alimentary paste ...is that of their stability to cooking , which means that, when cooked, the paste does not turn sticky and does not agglomerate into a gluey mass. [Salza; col. 1; line 33-37] (underline added for emphasis)

To promote the mutual dispersion of these two constituents in the mixture, small amounts [10%]... of monoglycerides ... are added as emulsifiers..."[Salza; col. 1; lines 51-54] (underline added for emphasis)

Salza explicitly teaches that the “fundamental problem” is the consistency of the paste (so that it does not agglomerate) and then, also explicitly, teaches that the solution to that problem is the inclusion of an emulsifier in relatively high concentration (*e.g.*, 10%, see Example 1, column 2, line 46.)

To the contrary, Applicants recognize the problem regarding consistency of the paste but instead discovered, through tedious experimentation, the advantageous and patently distinct features of the method of claim 1 for the preparation of low-gluten host wafers. In contrast to the Salza reference, this is accomplished without the addition of exogenous substances, such as emulsifiers, understanding that these may exacerbate alimentary disorders and/or violate Canon Law.

---

<sup>1</sup>Section 2 of Canon 924, Article 3 of the Code of Canon Law, 1983, from Book IV, Sanctifying Function of The Church, Part I, Sacraments, Title III, The Most Holy Eucharist, Chapter 1, Sacraments, Title III, The Most Holy Eucharist, Chapter 1 of the Eucharistic Celebration.

One of ordinary skill in the art reading the teachings of Salza would be taught that the fundamental problem of paste consistency is necessarily solved by the addition of an emulsifier and further that the lack of emulsifiers yields an unsuitable substance. Further, one of ordinary skill in the art upon reading “Western Communion Host” would understand the need for a low gluten communion wafer and that non-wheat components, such as an exogenous emulsifier, are unacceptable to the Roman Catholic Church.

After reading the “Western Communion Host” reference one skilled in the art would be reluctant to expose parishioners already suffering gastric disorders to an additive such as a relatively high amount of an emulsifier (10%). However, this is the teaching of the Salza reference. Taken together, the ordinary artisan would find that the “Western Communion Host” reference and the Salza reference are contradictory and not combinable. The teachings are in tension. Contrary to the assertion of the Examiner, one of ordinary skill in the art would be left with no expectation of success, and therefore no motivation to pursue of the advantageous features of the instant claim 1.

Accordingly, Applicants assert that the teachings of “Western Communion Host” in view of the Salza reference do not form a *prima facie* case of obviousness, as there would be no motivation for combination. Therefore, Applicants assert that rejection of the instant Claim 1 is improper under 35 U.S.C. §103(a), and respectfully request withdrawal of the rejection.

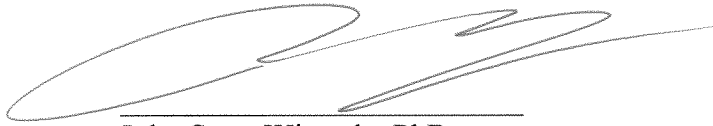
Instant dependent claims 4, 14 and 15 depend directly or indirectly from instant independent claim 1. The Applicants assert that instant independent claim 1 is non-obvious. In accordance with MPEP 2143.03, if an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious (*In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)) and the respective rejections should be rescinded.

CONCLUSION TO REMARKS

Applicants assert that this response is fully responsive to the Examiner's Office Action dated June 10, 2009. In view of the arguments presented, Applicants respectfully seek early allowance of the pending claims.

Dated: September 9, 2009

Respectfully Submitted,

A handwritten signature in black ink, appearing to read 'J. Winterle', is written over a horizontal line.

John Scott Winterle, PhD  
Reg. No. 57,276  
Kelley Drye & Warren LLP  
Intellectual Property Department  
400 Atlantic Street  
Stamford, CT 06901-3512

Direct Tel.: 203-351-8055  
Facsimile: 203-327-2669  
e-mail: [jwinterle@kelleydrye.com](mailto:jwinterle@kelleydrye.com)

**VI. APPENDIX**

- *No Appendix Included in this Response.*